

REMARKS

This communication responds to the Office Action of July 28, 2008, in which the Examiner rejected each of the pending claims. Reconsideration and allowance are respectfully requested at least for the reasons discussed below.

Rejection under 35 U.S.C. § 102(b)

Claim 1 was rejected under 35 U.S.C. § 102(b) as anticipated by Schankereli (US 5,782,914). This rejection is traversed at least for the following reasons.

Claim 1 recites a method effective to protect one or more properties of biological material during the process of sterilization “wherein providing a protective atmosphere within the packaging of the packaged biological material is carried out by at least partially removing an original atmosphere under vacuum, and replacing the original atmosphere with a reducing atmosphere or a mixture of an inert atmosphere and a reducing atmosphere”.

Preliminarily, in this, as in previous office actions, the Examiner has erroneously characterized “replacing the original atmosphere with a reducing atmosphere or a mixture of an inert atmosphere and a reducing atmosphere,” as recited by claim 1, as “replacing the original atmosphere with an inert atmosphere or a mixture of an inert atmosphere and a reducing atmosphere.” Specifically, the Examiner herein asserts:

Thus, Schankereli (sic) teaches a method wherein, (sic) it is the oxidation of material being processed that is prevented which is the logic behind conducting said processes in presence (sic) of an inert or an inert mixed with a reducing atmosphere.

Current Office Action, page 3; all so 12/27/07 Office Action, pages 5, 6, and 7. The Examiner thus reverses the use of inert and reducing atmospheres. The Applicant respectfully requests the Examiner to note the claim language and to view Schankereli in view of the stated claim language.

Schankereli does not disclose, teach, or suggest, “replacing the original atmosphere with a reducing atmosphere or a mixture of an inert atmosphere and a reducing atmosphere,” as recited by claim 1. Schankereli discloses a method for preparing heterogeneous graft material.

Schankereli, Col. 1, ll. 8-9. Vacuum-dried tissue specimens are inserted into a moisture-proof sterilizing pouch, which may be evacuated. *Schankereli, Col. 3, ll. 57-58.* Schankereli discloses that the atmosphere with the tissue package may be evacuated and/or replaced by an inert gas:

Evacuation and/or replacement of the atmosphere within the tissue package (the package containing the dried tissue) using a media such as argon or nitrogen limits free radical formation (oxidation) of the tissue during the sterilization process thus inhibiting chemical and physical changes to the tissue.

Schankereli, Col. 4, ll. 6-11. Each of argon and nitrogen are inert gases. Schankereli's disclosure of atmosphere replacement is limited to "a media such as argon or nitrogen" and, thus, an inert media. Schankereli does not disclose, teach, or suggest "replacing the original atmosphere with a reducing atmosphere or a mixture of an inert and a reducing atmosphere," as recited by claim 1. The Applicant respectfully requests the Examiner to contact the Applicant's representative should the Examiner remain confused as to this limitation and continue to construe this limitation with reducing and inert atmospheres reversed.

In explaining his rejection, the Examiner emphasized the logic for conducting processes in the presence of an inert or an inert mixed with a reducing atmosphere. Again, the present claims recite "replacing the original atmosphere with a reducing atmosphere or a mixture of an inert and a reducing atmosphere," not an inert atmosphere or an inert mixed with a reducing atmosphere. However, even assuming that the Examiner had correctly stated the claimed language, the Applicant respectfully notes that the inquiry behind an anticipation rejection is whether a references teaches every element of the claim; the logic behind the prior art or the claim is not relevant. MPEP 2131 discusses the requirements of a reference to anticipate a claim:

TO ANTICIPATE A CLAIM, THE REFERENCE MUST TEACH EVERY ELEMENT OF THE CLAIM: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

The Applicant respectfully submits that the logic for the prior art teachings and the logic for the claimed elements are not relevant, particularly when the prior art does not teach every element of the claim.

At best, Schankereli disclose a process wherein the atmosphere in a package may be replaced with an inert atmosphere. Schankereli does not disclose, teach, or suggest a method effective to protect one or more properties of biological material during the process of sterilization "wherein providing a protective atmosphere within the packaging of the packaged biological material is carried out by at least partially removing an original atmosphere under vacuum, and replacing the original atmosphere with a reducing atmosphere or a mixture of an inert atmosphere and a reducing atmosphere," as recited by claim 1. Reconsideration and allowance of claim 1 are thus respectfully requested.

Rejection under 35 U.S.C. § 103(a)

Claims 1, 32-35, 52 and 64 were rejected under 35 U.S.C. § 103(a) as obvious over the combined teachings from Schankereli (US 5,782,914) in view of Bertiger (US 4,538,757). This rejection is traversed at least for the following reasons.

As discussed above, Schankereli does not disclose, teach or suggest each of the elements of claim 1. The Examiner has relied on Bertiger for a reducing atmosphere that prevents oxide formation. The Examiner states:

Note that both Schankereli and Bertiger teach processes comprising exposure of material to be processed to an inert or a mixture of an inert and a reducing atmosphere to prevent damage to the material being processed, wherein said damage is because of the potential oxidation of said material (i.e., tissue or a device) during the heat generating process (i.e., gamma sterilization, or soldering).

Current Office Action, page 4. The Applicant first requests clarification regarding what the Examiner asserts is the teaching of each reference. As previously discussed, Schankereli teaches an inert atmosphere. Schankereli does not teach a reducing atmosphere, nor does Schankereli teach a combination of a reducing atmosphere and an inert atmosphere. Bertiger teaches a reducing atmosphere that is physically open to ambient atmosphere (discussed more fully

below). Bertiger does not teach a combination of a reducing atmosphere and an inert atmosphere.

Bertiger discloses a method and apparatus for wave soldering in a reducing atmosphere which prevents oxide formation and provides a fluxing action. *Bertiger, Col. 1, ll. 6-11*. The Bertiger apparatus and method for wave soldering eliminates the steps of fluxing and flux cleaning present in prior art wave soldering devices. *Bertiger, Col. 3, ll. 4-6*. A wave soldering apparatus 10 is contained primarily within an enclosure 12 having an entrance 13 and an exit 14. *Bertiger, Col. 2, ll. 4-6*. A conveyor apparatus 15 runs through the enclosure 12 (through the entrance 13 and out the exit 14). *Bertiger, Col. 2, ll. 7-9*. The atmosphere inside enclosure 12 is further controlled by an atmosphere supply apparatus 27 comprising a nitrogen gas supply 26, a hydrogen gas supply 28, a proportioning valve 29, and a gas inlet 30. *Bertiger, Col. 2, ll. 25-28*. Bertiger does not teach evacuating the enclosure 12 and uses only gas to minimize exchange of gases between the ambient atmosphere and the inside of the enclosure:

Nitrogen is thereby directed from nozzles 22, 23, 24 and 25 to form nitrogen gas curtains immediately inside entrance 13 and exit 14. In this manner, the exchange of gases between the ambient atmosphere and the inside of enclosure 12 is minimized.

The only manner by which exchange is minimized are "gas curtains," as shown in the Figure. Accordingly, Bertiger teaches wave soldering in a reducing environment. Bertiger does not teach evacuating the environment, does not teach replacing gas of the environment, does not teach an inert gas, and does not teach a combination of an inert gas and a reducing gas. Bertiger further does not teach sterilization and, at best, is concerned only with the oxides on metals when using heat in an oxidizing environment.

The Applicant respectfully asserts that, even if the Examiner had correctly interpreted the teachings of Schankereli and Bertiger, the combination of Schankereli with Bertiger is improper.

During many forms of sterilization for tissue suitable for use with the protective atmosphere, there is no heat. At least, any heat produced is generally at a level less than would destroy the biological properties of the tissue. Generally, concern arises from reaction of hydrogen directly with free radicals; this concern is independent of temperature rise. This may be contrasted with wave soldering; wave soldering relies on heat to remove oxidation products

from metal. Often, wave soldering occurs at temperatures over 600 degrees C. These temperatures are unsuitable for use with biological materials and the concerns that arise with such temperatures are thus not applicable to sterilization of biological materials. Thus, the concerns that arise with wave soldering may be widely variant from those that arise during irradiation, for example. The specific concerns that arise during sterilization and the specific concerns that arise during wave soldering are different. The way in which each of Schankereli and Bertiger solve these problems are, not surprisingly, different. The Examiner overgeneralizes both the problems and the solutions to say that they are the same.

MPEP 2141 discusses establishing a prima facie case of obviousness:

The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007) noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit.

The MPEP stresses the importance of providing articulated reasoning rather than mere conclusory statements in making a rejection under 35 U.S.C. 103:

The Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." In *re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). See also *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396 (quoting Federal Circuit statement with approval). <

The Examiner has not provided sufficient reason or explicit analysis of why the disclosure of Schankereli should be combined with Bertiger.

The Examiner has twice (in this and the previous office action) provided conclusory statements. In the current office action, the Examiner's conclusory statement is not only improperly conclusory but mischaracterizes the claims and each piece of prior art. The Examiner states that the logic behind Schankereli and Bertiger is the same and that they are solving the same problem in the same way:

Thus, in each case, it is the oxidation of material being processed that is prevented which is the logic behind conducting said processes in presence (sic) of an inert or an inert mixed with a reducing atmosphere, that is, they are solving the same problem in the same way.

Current Office Action, page 4. The Applicant again notes that the Examiner has mischaracterized the invention as well as the teachings of both Schankereli and Bertiger with respect to the teachings of inert atmospheres, reducing atmospheres, and mixtures of inert and reducing atmospheres. The Applicant further submits that Schankereli and Bertiger are not solving the same problem. Schankereli, in pertinent part, inhibits chemical and physical changes to tissue during the sterilization process. *Schankereli, Col. 4, ll. 6-11.* In contrast, Bertiger purports to eliminate the steps of fluxing and flux cleaning present in prior art wave soldering devices. *Bertiger, Col. 3, ll. 4-6.* Further, even if they were solving the same problem, they are clearly solving it in a different way, as implicit at least from the fact that Schankereli and Bertiger each have issued patents with divergent teachings having substantially no overlap in teachings.

With respect to irradiation in particular, hydrogen can react from free radicals from any source, including oxygen compounds in tissue (such as lipids). This may be contrasted with merely removing oxygen from air, for example by vacuum packaging. Vacuum packaging relies on vacuum to reduce oxygen content and so minimize oxidization. Vacuum packaging, however, will not remove oxygen compounds from tissue. It is for at least this reason that a protective atmosphere, such as a reducing gas atmosphere, may be useful.

The Applicant respectfully submits that the Examiner is using Applicant's invention as a template through a hindsight reconstruction of Applicant's Claim 1 to merely piece together references disclosing each of the limitations of Applicant's Claim 1, separately and independently, to arrive at Applicant's novel and advantageous method of protecting one or more properties of biological material during the process of sterilization. Bertiger has no relevance to the disclosure of Schankereli, which relates to the preparation and use of biological materials. Bertiger discloses wave soldering of printed circuit boards, for example, as they are run through an unevacuated enclosure 12 on a conveyor belt. No materials are packaged and sterilized. In fact, Bertiger does not disclose any need for packaging and sterilizing articles 17, 18, 19, and 20,

instead disclosing that once past the soldering apparatus, the articles are moved out of enclosure 12 by means of exit 14, back to the external atmosphere. Bertiger discloses only that the use of a nitrogen and hydrogen mixture allows a wave soldering procedure to be carried out in a non-oxidizing atmosphere and removes the need for a conventional fluxing agent. Removing articles from the non-oxidizing atmosphere and back into the external atmosphere would defeat the purpose of sterilization, which is the focus of Applicant's Claim 1.

In the previously response to office action, the Applicant explained in some detail the impropriety of combining the Schankereli and Bertiger references. In addition to failing to provide a detailed rationale for combining the references, the Examiner failed altogether to address the Applicant's previously submitted discussion of the impropriety of such combination. In order to expedite prosecution of the application, the Applicant respectfully requests that the Examiner acknowledge the Applicant's argument such that the Applicant's representative can clarify any questions the Examiner may have with respect to the argument.

The Applicant respectfully submits that the combination of Schankereli and Bertiger does not disclose each of the limitations of claim 1 and that, therefore, claim 1 is patentable over Schankereli and Bertiger, alone and in combination. The Applicant submits that Schankereli and Bertiger are not properly combinable and the rejection should further be Canceled for this reason. Each of the remaining rejected claims depends directly or indirectly from claim 1 and is allowable for the reasons discussed with respect thereto. Allowance of the claims is thus respectfully requested.

Request for Refund

Previously withdrawn claims 2-29, 31, 36-51, 53-63 and 66-88 have now been canceled. Applicant requests that the excess claim fees previously paid on the currently canceled withdrawn claims be refunded to Deposit Account No. 04-1420.

Conclusion

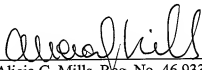
This application now stands in allowable form and reconsideration and allowance is respectfully requested.

This response is being submitted on or before March 19, 2009, making this a timely response. It is believed that no additional fees are due in connection with this filing. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

Respectfully submitted,

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